

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED CPAP,)	
BI-LEVEL PAP, AND MECHANICAL)	Master Docket: Misc. No. 21-1230
VENTILATOR PRODUCTS)	MDL No. 3014
LITIGATION,)	
)	
This Document Relates to: All Actions)	

**PLAINTIFFS’ OBJECTIONS TO THE DISCOVERY SPECIAL MASTER’S REPORT &
RECOMMENDATION (ECF 2069)**

Plaintiffs object to the Discovery Special Master’s Report & Recommendation (“R&R”) denying Plaintiffs’ Motion to Compel and granting Defendants’¹ Cross-Motion for Protective Order with respect to a third-party subpoena Plaintiffs issued to Exponent, Inc.

I. BACKGROUND

This dispute arises out of Defendants assertion of work product protection, and a later attorney-client privilege, over documents and communications responsive to a subpoena Plaintiffs issued to Exponent, Inc. (“Exponent”). In connection with Philips ongoing Class I Recall, Philips hired various companies to perform testing on the Recalled Devices, [REDACTED]
[REDACTED]
[REDACTED]. (See, e.g., PSN Report, Ex. 1.1). In an effort to obscure these results, Philips later hired Exponent to produce reports that claimed the chemicals emitted by Philips’s foam are not as highly toxic or carcinogenic as previous testing showed. Exponent’s role is hardly a surprise, and certain to be examined and challenged at a later date, given the role it has repeatedly played in other areas touching on public health and safety.²

¹ “Defendants” and “Philips” herein refer to the Philips Defendants identified in the R&R at n.1.

² See, e.g., Business Ethics Magazine, Big Companies in Legal Scrapes Turn to Science-For-Hire Giant Exponent, Dec. 13, 2016, available at <https://business-ethics.com/2016/12/13/1724-big-companies-in-legal-scrapes-turn-to-science-for-hire-giant-exponent/>; Michaels, David, *Doubt is Their*

In March 2022, the U.S. Food and Drug Administration (“FDA”) issued a 518(a) Order to Philips that, *inter alia*, directed Philips to have transparency with patients and providers with respect to the health risks associated with the Recalled Devices and testing results to date. (FDA 518(a) Notice, Ex. 4.B). Philips enlisted Exponent to draft these public disclosures purporting to summarize PE-PUR and volatile organic compound (“VOC”) testing results and conclusions (the “Summaries”),³ [REDACTED]

[REDACTED].⁴ Philips also had Exponent disclose certain written reports (the “Reports”) to the FDA.⁵

To the public and the FDA, Philips claimed [REDACTED]

[REDACTED]. (See Dec. 2021 FDA letter, Ex. 1.11 (“[REDACTED]

[REDACTED]”) (emphasis added)).^{6,7} [REDACTED]

Product: How Industry’s Assault on Science Threatens Your Health, Oxford University Press; 1st edition (April 23, 2008), ISBN: 978-0195300673.

³ See Summaries of PE-PUR Testing Results and Conclusions, dated Apr. 25, 2022, June 28, 2022, Dec. 21, 2022, and May 16, 2023, available at <https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/news/update-on-the-test-and-research-program>.

⁴ See Nov. 2021 email, Ex. 1.2 ([REDACTED]).

⁵ See Exponent’s Reports, Exs. 1.3-1.6, 2.B.

⁶ See also HHE, Ex. 1.9, pp. 5, 14 ([REDACTED] (emphasis added); June 2022 FDA letter, pp.20-21, Ex. 1.12 (“[REDACTED]”).

⁷ See Philips’s Voluntary Recall Information site, available at <https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/news/update-on-completed-set-of-test-results-for-home-sleep-therapy-devices> (“The test and research program has been conducted together with five independent, certified testing laboratories, and the results have been reviewed and assessed by third-party qualified experts [*i.e.*, Exponent] . . . Healthcare providers, patients, and other stakeholders should use the complete [testing] update (including information on the limitations of the testing) for any informed decision making.”)

██████████⁸ that was intended to assist the FDA “in determining the risk to the public from the defective product and appropriate actions for the [company] and the FDA to take to protect public health.”⁹ Philips’s pre-determined goal when it retained Exponent was to re-visit the prior conclusions of Philips and multiple truly independent labs. Notably, Philips does not assert work product protection with respect to any other consulting lab whose testing Philips disclosed to the FDA and the public, but nonetheless seeks to shield Exponent’s efforts to discredit those labs under such alleged protections.¹⁰

On July 22, 2022, Plaintiffs served a subpoena on Exponent for documents related to its work for Philips. (Subpoena, Ex. 1.13). Exponent ultimately produced redacted engagement agreements between Exponent and Philips’s counsel—one dated September 17, 2021 for Exponent to be a litigation consultant in this action (Sept. 2021 Engagement Agreement, Ex. 1.15), and another dated October 18, 2021 for general technical support regarding Philips’s devices (Oct. 2021 Engagement Agreement, Ex. 1.16). To date, Exponent has not produced a single document in response to the subpoena, advising that “Philips’ counsel has advised that *all* of Exponent’s work, *except for the final reports that have been provided to or summarized to the FDA*, are work product and privileged and, for those reasons, protected from disclosure.” (Oct. 2022 Exponent letter, Ex. 1.18) (emphasis added). Philips, despite being the party to assert privilege, refused to provide a privilege log, claiming that Exponent was a consulting expert. (See Nov. 30, 2022 Email chain, Ex. 1.20).¹¹

⁸ See Faulk Analysis, pp.6-7, Ex. 1.7; HHE, pp.5, 14, Ex. 1.9.

⁹ See FDA.gov, Health Hazard Evaluations (HHEs) and Health Risk Assessments (HRAs), <https://www.fda.gov/about-fda/cdrh-transparency/health-hazard-evaluations-hhes-and-health-risk-assessments-hras>.

¹⁰ Plaintiffs are aware that Exponent assisted Philips with “Science Day” and has assisted with the “visual device inspections.” Plaintiffs do not dispute that Exponent was serving as a consulting expert for those purposes and do not seek discovery of documents and communications related to those litigation activities.

¹¹ Philips’s suggestion of a logging exception is contradicted by the plain language of Pre-Trial Order 19 (ECF 661) and in light of Philips’s assertions while negotiating that Order that communications

On May 1, 2023, Plaintiffs moved to compel production of all undisclosed documents and communications related to the two discrete subject areas—the Reports and Summaries—that were disclosed by Philips to the FDA, (Plfs. Motion, Ex. 1), and Philips cross-moved for a Protective Order. (Defs. Motion, Ex. 4).¹² In relevant part, Plaintiffs argued that Philips had waived protections for at least some category of Exponent-possessed documents responsive to Plaintiffs’ subpoena, through the admittedly intentional public disclosure of the Reports and Summaries. Philips conceded that Exponent served in a dual-role as litigation consultant (retained by Philips’s counsel) and business consultant (retained by Philips directly), and that Philips had intentionally disclosed the Reports and Summaries and waived any protection for those materials. (*See* Defs. Opposition, p. 1, Ex. 2; Defs. Reply, p. 2, Ex. 6). Philips provided *no further detail or information* for Plaintiffs or the Special Master to ascertain what other documents, beyond the Reports and Summaries, exist or the scope of work was performed while wearing that, admittedly, non-privileged hat. Philips provided no declaration nor evidence with its motion, instead relying on bald assertions within the filing itself. (*See* Defs. Motion, Ex. 4; Defs. Opposition, Ex. 2).

This Court should not adopt the Special Master’s R&R. Philips has conceded it waived protections as to the Reports and Summaries, and because Philips has not produced a privilege log, Plaintiffs (and the Court) have no information regarding the nature and extent of documents and communications withheld purportedly pursuant to privilege or work-product protections, and as such cannot fully assess the scope of the waiver and whether any documents are improperly being

related to testing disclosed to the FDA *would* be logged so that Plaintiffs could assess the privilege. *See* Recording of July 6, 2022 Special Master Conference, at 21:50–24:30, Ex. 1.21.

¹² Notably, Philips did not assert work product protection with respect to any other consulting lab whose testing Philips disclosed to the FDA and the public, but nonetheless seeks to shield Exponent’s efforts to discredit those labs under such alleged protections. Plaintiffs are aware that Exponent assisted Philips with “Science Day” and has assisted with the “visual device inspections.” Plaintiffs do not dispute that Exponent was serving as a consulting expert for those purposes and do not seek discovery of documents and communications related to those litigation activities.

withheld at this time. Accordingly, the Court should require Philips to provide a privilege log with respect to the documents Philips directed Exponent to withhold from production so that Plaintiffs may properly assess the asserted privilege or protection for each document.

II. STANDARD OF REVIEW

The Court reviews *de novo* both the findings of fact and conclusions of law made or recommended by a Special Master. *See* Fed. R. Civ. P. 53(f)(3) and (4).

III. ARGUMENT

A. Any privilege or protection has been waived as to undisclosed documents related to the same subject matter as the disclosed Reports and Summaries.

A company waives work product protection where it discloses protected information to a potentially adversarial investigating government agency. *See Westinghouse Elec. Corp. v. Republic of Philippines*, 951 F.2d 1414, 1426, 1428 (3d Cir. 1991) (holding that a corporation’s voluntary disclosure of summary findings from its internal investigation and audit to the DOJ and the SEC while under investigation by both agencies waived *both* attorney-client privilege and work product protections as to all adversaries). When the disclosure of work product or attorney-client privileged information is made to a government agency, Rule of Evidence 502(a), enacted in 2008, provides that the waiver extends to undisclosed communications and information if: (1) the waiver is intentional; (2) the disclosed and undisclosed communications or information concern the same subject matter; and (3) they ought in fairness to be considered together. Fed. R. Evid. 502(a).

Philips concedes that it intentionally and voluntarily waived any work product protection by its disclosures to the FDA. (*See* Defs. Motion, Ex. 4; Defs. Opposition, Ex. 2). The balance of Rule 502(a) addresses the extent of that waiver, requiring a determination of what undisclosed documents are in the same subject matter and how much of that subject matter must be disclosed “in fairness.” *Bear Republic Brewing Co. v. Cent. City Brewing Co.*, 275 F.R.D. 43, 49 (D. Mass. 2011) (“In other

words, once the subject matter has been defined, how much information within that category must be disclosed because ‘in fairness,’ it should be ‘considered’ along with what has been disclosed?”).

Courts routinely find subject matter waiver where the disclosing party “attempt[s] to use the privilege as both a sword and a shield” or to present a one-sided story to the court. *See United States v. Coburn*, 2022 WL 357217, at *4 (D.N.J. Feb. 1, 2022) (quotation marks omitted); *In re Hum. Tissue Prod. Liab. Litig.*, 255 F.R.D. 151, 158 (D.N.J. 2008) (“[A] litigant cannot at one and the same time make use of those privileged communications which support his position while hoping to maintain the privilege as those communications which undercut his legal position.”). The Special Master appears to have used a narrow definition for “fairness” in reliance on the Advisory Committee Notes. (*See R&R*, at 8-9). But “the plain unambiguous wording of the Rule is what the law despite what is stated in either the Advisory Committee Notes or the legislative history.” *Bear Republic Brewing Co.*, 275 F.R.D. at 49. Typically, the advisory committee note, while a relevant consideration in the fairness element, is not considered a separate or required element for subject matter waiver. *See Rains v. Westminster Coll.*, 627 F. Supp. 3d 1267, 1278–79 (D. Utah 2022).

“The standard for fairness under Rule 502 is the same as for Fed. R. Evid. 106.” *Theranos, Inc. v. Fuisz Techs., Ltd.*, 2013 WL 2153276, at *3 (N.D. Cal. May 16, 2013). Under the Third Circuit’s Rule 106 standards, fairness requires subject matter waiver where the undisclosed evidence is necessary to (1) explain the disclosed documents; (2) place the disclosed documents in context; (3) avoid misleading the jury; or (4) insure a fair and impartial understanding of the disclosed documents. *See United States v. Evans*, 356 F. App’x 580, 583 (3d Cir. 2009) (citing *United States v. Soures*, 736 F.2d 87, 91 (3d Cir.1984)); *In re County of Erie*, 546 F.3d 222, 229 (2d Cir.2008) (Subject matter waiver must be determined on a “case-by-case basis” and is justified “when a party uses an assertion of fact to influence the decisionmaker while denying its adversary access to privileged materials potentially capable of rebutting the assertion.”).

Here, although Plaintiffs have no privilege log to understand the scope of Exponent's withholding of documents, there can be no dispute that there must be materials underlying Exponent's disclosed Reports and Summaries that relate to the same subject matter and, in fairness, ought to be considered together with the Reports and Summaries.¹³ In such circumstances, Courts routinely find waiver. *See, e.g., Coburn*, 2022 WL 357217, at *7 (because Cognizant provided the DOJ with summaries of its internal investigation while under the threat of prosecution, the Court found that "to the extent that summaries of interviews were conveyed to the government . . . the privilege is waived as to all memoranda, notes, summaries, or other records of the interviews themselves."); *City of Capitola v. Lexington Ins. Co.*, 2013 WL 1087491, at *2 (N.D. Cal. Mar. 13, 2013) ("Following [plaintiff's] voluntary disclosure of part of [consultant's] investigation, [defendant] now is entitled to see [consultant's] entire investigation."). Philips has already used, and has expressed that it intends to continue using, Exponent's Reports and Summaries as evidence in this litigation. While Philips seeks to use the disclosed documents as a sword, it improperly attempts to shield the related, underlying documents. *See In re King's Daughters Health Sys., Inc.*, 31 F.4th 520, 528 (6th Cir. 2022) ("disclosure of some information regarding its experts' study waived its privilege over the related, undisclosed information"); *Rains*, 627 F. Supp. 3d at 1280 ("Fairness also dictates the other undisclosed documents relating to the Durham investigation should be considered together with the disclosed reports.").

The Special Master concluded that Plaintiffs possess all the necessary materials from Exponent because the final reports were produced with their attachments. (*See* R&R, p. 8). This is incorrect. Exponent was directed by Philips to withhold *all* documents responsive to the subpoena

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See Ex. 1.5, p. 8–9. Those documents have not been produced to date and would wrongly be categorized as privileged if the protective order recommended by the R&R is granted. Plaintiffs should be permitted to fully investigate the assumptions provided by Philips underlying the Reports' and Summaries' conclusions.

under Philips's assertion of privilege. (Ex. 1-18). Philips modified that position in its May 1, 2023 motion, stating that Plaintiffs would receive various documents including, for example, communications between Exponent and the other labs. (*See* Def. Motion, p. 2). However, nearly three months have passed since Philips made that representation and Exponent has failed to produce a single document in response to Plaintiffs' subpoena, including not even a single communication between Exponent and any third party.¹⁴ Moreover, because no privilege log has been produced, Plaintiffs continue to operate in the dark as to what documents exist or what documents have been withheld.

As one example, in its [REDACTED]

[REDACTED] (Exponent's March 2023 Report, p. 41, Ex. 2.B).

However, the FDA previously concluded that Philips's justification for dismissing these test results was not persuasive.¹⁵ Nevertheless, [REDACTED]

[REDACTED]. (Exponent's March 2023

¹⁴ Exponent submitted a letter to the Special Master on May 1, 2023 asserting burden and purporting to support Philips's submission. *See* Ex. 6. Plaintiffs opposed that submission because, *inter alia*, timely objections were not made, nor was a timely protective order sought as required under Fed. R. Civ. P. 45. *See* Ex. 7. The Special Master did not address Exponent's submission in her R&R.

¹⁵ FDA 518(b) Notice, p. 4, available at <https://www.fda.gov/media/158129/download> ("[Philips's] summary suggested that certain tests that produced results supporting the conclusion that the recalled devices present a significant risk suffered from limitations and should be discounted, and emphasized tests that produced results identifying no risks. However, Philips'[s] summary included justifications for discounting the previously conducted tests that CDRH does not find persuasive, and Philips excluded from its risk assessment prior tests that showed cytotoxicity failure and compounds of concern.").

Report, p. 41, Ex. 2.B). The undisclosed documents will bear *directly* on the reliability and evidentiary value of the disclosed Reports and Summaries.

The Special Master also stated that Plaintiffs rely on speculation for the assertion the fairness favors waiver in this instance. Here, again, Plaintiffs respectfully object to the Special Masters' conclusion. Because Plaintiffs lack access to the documents and because Philips has not produced a privilege log of the withheld documents, it is unavoidable that Plaintiffs cannot state with certainty what documents have been withheld and some speculation—informed by the evidence—is required. Working with these unavoidable limitations, Plaintiffs provided substantial evidence to support their argument that Philips waived protection over some swath of Exponent-controlled documents, and that fairness requires disclosure. Philips has repeatedly [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. (See Draft HHE, p.5, N. Nandhagopal Comment at NN22R21, Ex. 1.28).

At bottom, Philips intentionally and voluntarily disclosed Exponent's Reports and Summaries. Simultaneously, it maintains that no other documents possessed by Exponent may be produced pursuant to Plaintiffs' subpoena. It would be manifestly unfair were Philips permitted to strategically disclose only certain documents while hiding additional documents indisputably related to the same

subject and necessary to avoid misleading the finder of fact. Rule 502 is intended to prevent this precise circumstance, where a party makes selective disclosures to support its position while simultaneously concealing documents or communications that do not. *North Dakota v. United States*, 64 F. Supp. 3d 1314, 1346–47 (D.N.D. 2014). Here, fairness requires that Plaintiffs be able to explore those undisclosed documents.¹⁶

This Court should not adopt the R&R and should hold that subject matter waiver applies and should either grant Plaintiffs’ motion to compel all documents and communications related to the Reports and Summaries, or should define the scope of the subject matter waiver that the Court deems proper and dictated by fairness.

B. In light of Philips’s assertion of Exponent’s dual role, Philips should produce a privilege log consistent with Pre-Trial Order 19.

The “burden of demonstrating that a document is protected as work-product rests with the party asserting the doctrine,” here, Philips. *In re: Maxim Integrated Prod., Inc.*, 2013 WL 12141533, at *5 (W.D. Pa. July 17, 2013) (Conti, J.) (citing *Conoco, Inc. v. U.S. Dep’t of Justice*, 687 F.2d 724, 730 (3d Cir. 1982)). Further, the “work product doctrine only protects documents prepared in anticipation of litigation, not the regular course of business.” *York Grp., Inc. v. Pontone*, 2012 WL

¹⁶ The R&R included an analogy to Rule 26(b)(4)(B) with respect to special or exceptional need, claiming that because draft reports are not discoverable from testifying experts, Plaintiffs should not be provided drafts from non-testifying experts. *See* R&R, p. 13. Because the protections of Rule 26 were waived with respect to the Reports and Summaries, and because Fed. R. Evid. 502 governs the scope of the waiver, Rule 26 does not apply in this context. However, it is notable that Plaintiffs would receive far greater discovery from a testifying expert than the Special Master has permitted with respect to the Exponent Reports and Summaries, placing Plaintiffs at a serious disadvantage in preparing to depose Exponent and to address the Report and Summaries as this litigation proceeds. *See Plymovent Corp. v. Air Tech. Sols., Inc.*, 243 F.R.D. 139, 143 (D.N.J. 2007) (“discovery with respect to testifying experts is essential to allow opposing counsel to adequately prepare for cross-examination, and to eliminate surprise at trial”). For instance, Exponent has not produced, and the protective order as recommended would protect all internal correspondence of Exponent regardless of the subject, communications regarding compensation and assumptions, and all documents and communications related to all facts and data considered (not just relied upon) by Exponent. A testifying expert would be subject to much greater discovery than Plaintiffs are being permitted under the R&R.

12895527, at *2 (W.D. Pa. Apr. 2, 2012) (Conti, J.) (citing *Highland Tank & Mfg. Co. v. B.S. Intern, Inc.*, 246 F.R.D. 239, 246 (W.D. Pa. 2007)).

The Special Master accepted that the engagement agreement, with nothing more, dictated a finding that Exponent was a consulting expert¹⁷ and, based in part on this, recommended a broad protective order as to all documents and communications underlying the Reports and Summaries. (See R&R, generally). Philips's motion for protective order rests on a "just trust us" suggestion by Defendants that (presumably) Exponent will produce anything Philips deem to be relevant and not privileged or protected, and will withhold any documents Philips believes are privileged or protected. The Special Master provided a blanket protection over Exponent's documents by granting Philips's Motion for Protective Order, and excusing Philips's requirement under Pre-Trial Order 19 to provide a privilege log. This approach is concerning. Here, Philips already shifted from its initial position in October 2022 that *everything* responsive to the subpoena other than the Report and Summaries that were actually disclosed to the FDA is privileged or protected, (see Exponent Oct. 2022 letter, Ex. 1.18), to Philips's claims that certain documents related to Exponent's work were being produced, (See Defs. Motion, Ex. 4), to Philips's even more recent admission that Exponent performed admittedly non-privileged, currently unspecified work as a business consultant to Philips, (See Defs. Opposition, p. 1, Ex. 2; Defs, Reply, p. 2, Ex. 6).

Philips chose to intermingle Exponent as a business and litigation consultant. Where an expert serves *both* as a litigation and a business consultant, such as Exponent here, documents and communications related to work as a business consultant are discoverable. See *In re Painted Aluminum Products Antitrust Litigation*, 1996 WL 397472, at *2, n.2 (E.D. Pa. July 9, 1996) (What is "worrisome is the possibility that a party may utilize the dual purpose rationale to cloak legitimate

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. See, e.g., Van Dyke Retainer Email, Ex. 1.17.

witnesses.”); *UPMC v. CBIZ, Inc.*, 2018 WL 1542423, at *8 (W.D. Pa. Mar. 29, 2018) (a document created for a dual-purpose of business needs and for use in litigation is not privileged); *AMP, Inc. v. Fujitsu Microelectronics, Inc.*, 853 F. Supp. 808, 830 (M.D. Pa. 1994) (rejecting privilege assertion because “in-house counsel may serve dual functions, acting as both legal counsel and business counsel,” and plaintiff failed in its burden to show that the memorandum was for the former). Seemingly accepting Philips’s form over substance approach, the Special Master found that the engagement agreements, with nothing further, dictate the outcome of the dispute. But the R&R fails to account for how to parse the dual roles that Exponent serves, particularly in light of Philips providing no evidence with respect to what hat Exponent wore at what instances.

The Special Master recommends granting a broad protective order over a wide array of documents, without any requirement for a privilege log. Absent the production of a privilege log consistent with the Privilege Log Protocol, Plaintiffs are unable to assess whether Exponent is withholding non-privileged documents under a flawed assertion of privilege, or under the guise of the protective order where the work was performed while Exponent wore a business consultant hat.

This Court should not adopt the R&R; however, if it does, it should Order Philips to produce a privilege log of all documents responsive to the subpoena it directs Exponent to withhold on the basis of privilege or protection thereby affording Plaintiffs an opportunity to properly challenge those assertions.

Dated: July 19, 2023

Respectfully submitted,

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